Report
ISSC *V. parahaemolyticus* Subcommittee Meeting
Las Vegas, NV
August 9-10, 2004

All Subcommittee participants were present:

Paul Comar (Chair)	Jennifer Tebaldi	Kirk Wiles
Lori Howell	Mike Hickey	David Heil
Don Kraemer	Kathy Brohawn	Robin Downey
Bill Hastback	Bill Kramer	Angela Ruple
Eric Feerst	Klaus Schallie	Chris Nelson
Bob Collette	Dan Leonard	

Speaker participants:

Andy DePaola (FDA)	John Painter (CDC)

The meeting agenda is attached to indicate how the subcommittee addressed the following tasks assigned to the group for 2004-2005:

- Identify and evaluate alternate control that would address sporadic cases of *Vp*. Develop recommendations for the 2005 Biennial Meeting.
- Finalize the prioritized list of research needs.
- Continue efforts to enhance the CDC report form to include additional epidemiological and environmental information. Include harvest location and date of harvest.
- Provide clarification to the instructions for data collection.
- Complete the 2002 data summary table.

State *Vp* Reporting

State 2003 *Vp* illness reports were discussed. In February 2004 the ISSC Exec. Office sent a letter to state epidemiologists and other state offices requesting *Vp* illness data as previously formatted and requested in 2002. These data were requested for three primary purposes: 1) to better determine the number of illnesses and source of shellfish, 2) to better understand the different *Vp* reporting practices among the states, and 3) to use cases reported to help determine when the current *Vp* Interim Control Plan (*Vp* ICP) guidance might be used by state agencies.

Of the 23 coastal states, the ISSC received 18 responses with 13 state reports provided to the *Vp* subcommittee. There was also a single response from Pennsylvania. Of the 13 state responses, there were approximately 20 illnesses reported, and of these, 4 could not be traced to the producing state. Difficulty in documenting *Vp* cases and obtaining reports centers on its relative low public health importance from the perspective of most state epidemiologists – the low number of cases identified, most are reported as single cases vs. outbreaks, and symptoms are usually mild to moderate gastrointestinal of short duration.

Reporting from all fifty states could provide greater insight regarding the incidence of *Vp* nationally, but acquiring illness reports from all fifty states presents significant challenges. The purpose of an ISSC Vp illness survey would not be well understood by state epidemiologists in non-NSSP participating states. Communications with the Council of State and Territorial Epidemiologists (CSTE) would be necessary to accomplish involvement from non-NSSP participating states.

A more significant impediment is the simple fact that *Vp* is not a reportable illness in all states. Comparing information from states that have established *Vp* as a reportable illness to those that have not is problematic, particularly if the purpose is to extrapolate a national incidence rate for comparison to the rate projected by CDC in its *Vp* risk assessment. To present, the ISSC has received *Vp* illness data only from NSSP participating states. Preparing the table recommended under item ii below would assist the subcommittee in interpreting annual reports, recognizing the inconsistency in "reportable" status is likely to continue.

Other items from the *Vp* illness report discussion that the subcommittee chair will help resolve with the Executive Office:

i. Prepare a short tabular record of large *Vp* outbreaks and those of the 2-3 case variety reported since 1997.

ii. Prepare a table indicating states where *Vp* is reportable vs. those where it is not.

iii. Resolve whether CDC or some other body might request and compile *Vp* illness reports for the ISSC instead of the ISSC requesting reports of the state.

FDA *Vp* Risk Assessment

Andy DePaola delivered a detailed presentation, distributed handouts of presentation slides, and answered questions on the latest draft of FDA's *Vp* Risk Assessment. The report, in draft since 2001, may be released by the end of 2004, but FDA may be able to release parts of it sooner under restrictions to interested subcommittee members. Among the information Dr. DePaola discussed over several hours was the scope of the risk assessment; nature of and rationale for assumptions made in the Harvest, Post-Harvest and Consumption Modules of the assessment; data and sources used in risk modeling, seasonal estimates of illnesses in six regions (Pacific Northwest (dredged), Pacific NW (intertidal), Mid-Atlantic, North Atlantic, Gulf-LA, Gulf other than LA); and estimates of the effects of various measures (including more rapid cooling of oyster shellstock) in mitigating risk. He also described validation of models; requested that states work with offices of the FDA to use state data to help individualize the models for use in certain locations and seasons; and outlined a study underway using satellite-derived water temperature data to improve the models with better spatial and temporal water temperature data, a dominant factor in the models.

Many questions and comments were discussed. It is not possible to summarize or draw a consensus from the range of subcommittee discussion, but the Risk Assessment is better understood and appreciated in its methods and outcomes based on assumptions and data used.

CDC *Vp* Illness Estimates

John Painter made a presentation on methods CDC used in predicting there are 2800 *Vp* illness cases per year - the estimate FDA used in its Risk Assessment. Dr. Painter sent a summary of the information to the *Vp* subcommittee at its prior meeting, and he took this opportunity to describe how the estimate was reached, starting at the basics of illness onset through reporting to CDC and finishing with the stepwise procedures and source of numbers and data CDC used in generating its estimate. Much discussion followed with some on the subcommittee feeling the number is high based on actual *Vp* cases reported while others view it as a reasonable or perhaps an even low estimate. So while consensus was not evident, there was a clearer understanding of how the estimate was reached and that the approach used was valid.

Alternate *Vp* Control Measures

The subcommittee considered its charge to evaluate illness risk control alternatives to the *Vp* ICP now included as guidance (not a satisfactory compliance element) in the Model Ordinance. We began with discussion from states that had been using the guidance based on prior year *Vp* cases. Most felt that there was some utility in *Vp* monitoring associated the *Vp* ICP. Monitoring can produce a record of potentially high *Vp* harvest areas, though high total *Vp* does not necessarily imply high levels of pathogenic *Vp* and thus higher risk. Monitoring and use of results has benefited some states in communication with industry about harvesting in certain locations and steps (shading, more rapid chilling of shellstock after harvest, etc.) taken to limit *Vp* increases post harvest. However, the extent of monitoring is generally viewed now as insufficient to help prevent *Vp* outbreaks as originally intended. Costs and time demands of more extensive monitoring would be both impractical and of minimal utility as an illness outbreak mitigation strategy. Most states using monitoring for *Vp* indicated they intend to continue monitoring at some level for the purposes previously noted.

Discussion continued on the options for potential new or revised *Vp* control strategies, including further review of data gaps that if filled may improve the risk assessment and CDC annual illness estimate. It was acknowledged that although both are estimates from models which could be improved with more data. They are useful now in considering future or revised controls. FDA's Risk Assessment identified harvest water temperature as a major factor, and FDA requested that the subcommittee develop and recommend controls, such as more rapid cooling of shellstock harvested from warm waters, as Satisfactory Compliance Issues for deliberation at the 2005 ISSC biennial meeting. Various state and industry representatives did not agree with this approach at this time based on questioned elements of the risk assessment, lack of agreement of the significance of the public health risk, potential serious economic impacts to the industry, increased focusing of limited state regulatory resources to *Vp* controls and away from other shellfish safety controls, and lack of defined measures to indicate resulting risk reductions based on mandatory controls.

The consensus of the Subcommittee was that *Vp* illnesses are a concern and that additional guidance (not Satisfactory Compliance elements) to states and industry for reducing risks was

the appropriate response. The subcommittee recommended revising the *Vp* ICP guidance with producing states developing a *Vp* management plan. Guidance should include optional control strategies that have the potential to reduce the risk of *Vp* illness and an industry communication element. A workgroup was assigned to revise or develop a new *Vp* ICP considering its existing elements, CDC's annual *Vp* illness estimate, the FDA Risk Assessment (including proposed risk reduction strategies), and other pertinent information such as both positive and negative regulatory and economic impacts of implementing new guidance. An idea receiving support was the concept of developing a "toolbox" of various *Vp* control measures or options based upon season, region, state or other local factors. The workgroup will develop the revised guidance as a draft for review at the 2005 committee meeting associated with the March 2005 ISSC Executive Board meeting. The Subcommittee will review the draft for possible submission as a proposal to the 2005 Biennial Meeting.

Workgroup members are Don Kraemer and Angela Ruple (federal); Eric Feerst and Kirk Wiles (state); and Robin Downey and Lori Howell (industry). Deb Cannon (state) and Chris Nelson (industry) will be asked to participate as well.

<u>*Vp* Research Priorities</u>

The subcommittee also designated a short list of highest priority research data and information needs based on its previous research rankings (distributed April, 2004) for improving the Risk Assessment and clarifying risk management options. In short those research priorities are:

i. Conduct a study of total and pathogenic *Vp* (tlh, tdh, trh) and possibly Vv at retail to include lots traced from harvest through 1st dealer to retail. It's very important that the study be designed to determine seasonally and regionally the % *Vp* of total *Vp* that is pathogenic.

ii. Conduct a survey to determine the percentage of the total harvest of oysters that are consumed raw. An effort is nearly complete for the Gulf States, and there was interest in extending it to other regions.

iii. Determine the effects on *Vp* levels of various harvest/handling practices. There is a partnered project funded to LSU that might serve as the basis for some

determinations, in Louisiana. FDA's Andy DePaola will review the objectives of this proposal and discuss with a small *Vp* research workgroup that study's alignment with ISSC interest. There may also be an interest in determining if and how practices in other states might be evaluated. The study should include some estimates of economic and investment costs.

Andy DePaola, Angela Ruple, and Mike Hickey volunteered to serve on a *Vp* research workgroup, and Daniel Cheney (Pacific Shellfish Institute) will be asked to serve as well. The workgroup is tasked to design and recommend next steps on the three items above.

Other Items and Requests

A request was made that the Executive Board ask CDC to prepare two additional *Vp* illness estimates – 1) average annual number based on same method of estimate but include year 2003 to the previous 1998-2002 summary number of cases and 2) same as above but drop 1998 (an outbreak year) since the *Vp* Risk Assessment was developed for sporadic cases.

A request was made that the FDA prepare a full cost/benefit assessment of implementing various harvest and post-harvest *Vp* reduction practices for designated segments of the industry.

Agenda
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August 9

8:00 AM	Welcome, role call, review subcommittee charge, and review/revise agenda
8:15 AM	Review 2003 and 2002 *Vp* illness report data; consider any instruction changes
9:15 AM	Presentation: *Vp* Illness Estimates and Discussion - CDC
10:15 AM	Break
10:30 AM	Presentation: Draft *Vp* Risk Assessment and Current Perspective – FDA
12:00 Noon	Lunch
1:15 PM	Discussion of the Risk Assessment and Illness Estimates
3:00 PM	Break
3:15 PM	Alternate controls for sporadic *Vp* cases
4:15 PM	Review and finalize *Vp* priority research list
5:00 PM	Adjourn

August 10

8:00 AM	Review First Day
8:30 AM	Alternate controls for sporadic *Vp* cases (continued)
10:00 AM	Break
10:15 AM	Complete discussions
11:15 AM	Outline *Vp* Subcommittee Findings and Recommendations
12:00 Noon	Adjourn